**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| WYETH,<br><br>Plaintiff,<br><br>v.<br><br>IMPAX LABORATORIES, INC.,<br><br>Defendant. | Civil Action No.: 06-222 JJF |

**STIPULATION TO FILE FIRST AMENDED ANSWER, AFFIRMATIVE DEFENSES, COUNTERCLAIMS AND PRAYER FOR RELIEF OF DEFENDANT IMPAX LABORATORIES, INC.**

IT IS HEREBY STIPULATED by the parties, as follows:

1. Impax Laboratories, Inc. ("Impax") will file its First Amended Answer, Affirmative Defenses, Counterclaims And Prayer For Relief ("the FAA"), attached hereto as Exhibit A, on or before the current deadline for the parties to amend the pleadings, which is August 10, 2006.

2. Wyeth hereby consents to Impax's filing of the FAA. In so doing, Wyeth strenuously disagrees with Impax's allegations therein and reserves all of its rights, claims, and defenses.

Dated: August 10, 2006

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# EXHIBIT A

**IN THE UNITED STATES DISTRICT COURT**

**FOR THE DISTRICT OF DELAWARE**

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|---|---|---|
| WYETH, | ) | |
| Plaintiff, | ) | |
| | ) | Civil Action No.: 06-222 JJF |
| v. | ) | |
| IMPAX LABORATORIES, INC., | ) | |
| Defendant. | ) | |

**FIRST AMENDED ANSWER, AFFIRMATIVE DEFENSES, COUNTERCLAIMS AND PRAYER FOR RELIEF OF DEFENDANT IMPAX LABORATORIES, INC.**

Defendant and Counterclaim Plaintiff Impax Laboratories, Inc. ("Impax") hereby answers the numbered paragraphs of the Complaint for Patent Infringement of Plaintiff Wyeth ("Wyeth") as follows:

**THE PARTIES**

1. On information and belief, Impax admits that Wyeth is a Delaware corporation having its principal place of business at Five Giralda Farms, Madison, New Jersey 07940.

2. Impax admits that it is a Delaware corporation having its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544, and that it has a place of business at 3735 Castor Avenue, Philadelphia, Pennsylvania 19124. The remaining allegations of Paragraph 2 of the Complaint are denied.

**NATURE OF THE ACTION**

3. Impax admits that the Complaint purports to state a cause of action under the United States patent laws relating to an Abbreviated New Drug Application ("ANDA"), filed by Impax with the U.S. Food and Drug Administration ("FDA") for

approval to market a generic version of Wyeth's EFFEXOR® XR drug product sold in the United States. Impax denies the remaining allegations of Paragraph 3 of the Complaint.

**JURISDICTION AND VENUE**

4. Impax admits the allegations contained in Paragraph 4 of the Complaint.

5. Impax admits that it is incorporated in Delaware and has appointed a registered agent in Delaware. The remaining allegations of Paragraph 5 of the Complaint are denied.

6. For the purpose of answering this Complaint, Impax admits the allegations contained in Paragraph 6 of the Complaint.

7. For the purpose of answering this Complaint, Impax admits that venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(c) and 28 U.S.C. § 1400(b).

**BACKGROUND**

8. On information and belief, Impax admits that Wyeth is the holder of New Drug Application ("NDA") No. 20-699 for EFFEXOR® XR Capsules, a purported extended release dosage form containing Venlafaxine Hydrochloride. Impax lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 8 of the Complaint and on that basis denies each and every such allegation.

9. Impax admits that it filed an ANDA with the FDA, and that the FDA has assigned to the ANDA No. 78-057 under 21 U.S.C. § 355(j). Impax also admits that this ANDA was filed in order to obtain approval for the commercial manufacture, use, and sale of Venlafaxine HCl Extended-Release Capsules, in 37.5, 75, and 150 mg dosage strengths. Impax admits that it is seeking approval for generic versions of Wyeth's EFFEXOR® XR Capsules in 37.5, 75, and 150 mg dosage strengths. Impax denies the remaining allegations in Paragraph 9 of the Complaint.

10. Impax admits that in a letter dated February 21, 2006, Impax notified Wyeth that it had filed an ANDA seeking approval to market Venlafaxine HCl Extended-

Release Capsules, in 37.5, 75, and 150 mg dosage strengths, and that it was providing information to Wyeth pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95. Impax admits that Wyeth received this letter on February 22, 2006. Impax lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 10 of the Complaint and on that basis denies each and every such allegation.

**FIRST COUNT FOR INFRINGEMENT OF UNITED STATES PATENT NO. 6,274,171 B1**

11. Impax admits that U.S. Patent No. 6,274,171 B1 ("the '171 patent"), entitled "Extended Release Formulation of Venlafaxine Hydrochloride," was issued on August 14, 2001, and recites American Home Products Corporation as the assignee, but denies that it was duly and legally issued. Impax admits that Exhibit A to the Complaint appears to be a true and correct copy of the '171 patent. Impax lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 11 of the Complaint and on that basis, denies each and every such allegation.

12. Impax admits that it filed ANDA No. 78-057 in order to obtain approval to market its Venlafaxine HCl Extended-Release Capsules in the United States before the expiration of the '171 patent, but denies that its venlafaxine products infringe any valid and enforceable claim of the '171 patent. Impax also admits that this ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), asserting that the claims of the '171 patent were not infringed, and are invalid and/or unenforceable. The remaining allegations of Paragraph 12 of the Complaint are denied.

13. Impax denies each and every allegation in Paragraph 13 of the Complaint.

14. Impax denies each and every allegation in Paragraph 14 of the Complaint.

15. Impax denies each and every allegation in Paragraph 15 of the Complaint.

16. Impax denies each and every allegation in Paragraph 16 of the Complaint.

17. Impax denies each and every allegation in Paragraph 17 of the Complaint.

18. Impax denies each and every allegation in Paragraph 18 of the Complaint.

19. Impax denies each and every allegation in Paragraph 19 of the Complaint.

20. Impax denies each and every allegation in Paragraph 20 of the Complaint.

21. Impax denies each and every allegation in Paragraph 21 of the Complaint.

**SECOND COUNT FOR INFRINGEMENT OF UNITED STATES PATENT NO. 6,403,120 B1**

22. Impax admits that U.S. Patent No. 6,403,120 B1 ("the '120 patent"), entitled "Extended Release Formulation of Venlafaxine Hydrochloride," was issued on June 11, 2002, and recites Wyeth as the assignee, but denies that it was duly and legally issued. Impax admits that Exhibit B to the Complaint appears to be a true and correct copy of the '120 patent. Impax lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 22 of the Complaint and on that basis, denies each and every such allegation.

23. Impax admits that it filed ANDA No. 78-057 in order to obtain approval to market its Venlafaxine HCl Extended-Release Capsules in the United States before the expiration of the '120 patent, but denies that its venlafaxine products infringe any valid and enforceable claim of the '120 Patent. Impax also admits that this ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), asserting that the claims of the '120 patent were not infringed, and are invalid and/or unenforceable. The remaining allegations of Paragraph 23 of the Complaint are denied.

24. Impax denies each and every allegation in Paragraph 24 of the Complaint.

25. Impax denies each and every allegation in Paragraph 25 of the Complaint.

26. Impax denies each and every allegation in Paragraph 26 of the Complaint.

27. Impax denies each and every allegation in Paragraph 27 of the Complaint.

28. Impax denies each and every allegation in Paragraph 28 of the Complaint.

29. Impax denies each and every allegation in Paragraph 29 of the Complaint.

30. Impax denies each and every allegation in Paragraph 30 of the Complaint.

31. Impax denies each and every allegation in Paragraph 31 of the Complaint.

32. Impax denies each and every allegation in Paragraph 32 of the Complaint.

**THIRD COUNT FOR INFRINGEMENT OF UNITED STATES PATENT NO. 6,419,958 B2**

33. Impax admits that U.S. Patent No. 6,419,958 B2 ("the '958 patent"), entitled "Extended Release Formulation of Venlafaxine Hydrochloride," was issued on July 16, 2002, and recites Wyeth as the assignee, but denies that it was duly and legally issued. Impax admits that Exhibit C to the Complaint appears to be a true and correct copy of the '958 patent. Impax lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 33 of the Complaint and on that basis, denies each and every such allegation.

34. Impax admits that it filed ANDA No. 78-057 in order to obtain approval to market its Venlafaxine HCl Extended-Release Capsules in the United States before the expiration of the '958 patent, but denies that its venlafaxine products infringe any valid and enforceable claim of the '958 patent. Impax also admits that this ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), asserting that the claims of the '958 patent were not infringed, and are invalid and/or unenforceable. The remaining allegations of Paragraph 34 of the Complaint are denied.

35. Impax denies each and every allegation in Paragraph 35 of the Complaint.

36. Impax denies each and every allegation in Paragraph 36 of the Complaint.

37. Impax denies each and every allegation in Paragraph 37 of the Complaint.

38. Impax denies each and every allegation in Paragraph 38 of the Complaint.

39. Impax denies each and every allegation in Paragraph 39 of the Complaint.

40. Impax denies each and every allegation in Paragraph 40 of the Complaint.

41. Impax denies each and every allegation in Paragraph 41 of the Complaint.

42. Impax denies each and every allegation in Paragraph 42 of the Complaint.

43. Impax denies each and every allegation in Paragraph 43 of the Complaint.

## AFFIRMATIVE DEFENSES

### FIRST AFFIRMATIVE DEFENSE
### (Noninfringement)

44. Impax is not infringing, has not infringed, nor will it infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '171 patent, the '120 patent, or the '958 patent (collectively "the Patents-in-Suit").

### SECOND AFFIRMATIVE DEFENSE
### (Prosecution History Estoppel)

45. An additional basis of non-infringement is that statements, representations, admissions, and amendments made to the U.S. Patent and Trademark Office ("PTO") during the prosecution of the applications which matured into the Patents-in-Suit, as well as the prior art, estops Wyeth from asserting that the claims of said patents are infringed by any product of Impax.

### THIRD AFFIRMATIVE DEFENSE
### (Invalidity)

46. The Patents-in-Suit and each of the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, utility, anticipation, obviousness, lack of enablement, lack of written description, indefiniteness, and misjoinder/nonjoinder of named inventors in accordance with 35 U.S.C. §§ 101,102, 103, 112, and/or 116, or are invalid pursuant to the judicial doctrine barring double-patenting.

### FOURTH AFFIRMATIVE DEFENSE
### (Unclean Hands)

47. The Patents-in-Suit are unenforceable because Wyeth has unclean hands.

**FIFTH AFFIRMATIVE DEFENSE**
**(Inequitable Conduct)**

48. The Patents-in-Suit and each of the claims thereof are unenforceable because of the patentees' inequitable conduct, as alleged more specifically in Impax's Second Counterclaim, set forth below.

**COUNTERCLAIMS FOR AFFIRMATIVE RELIEF**

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Impax hereby asserts counterclaims against Wyeth as follows:

49. Impax realleges and incorporates by reference its responses and allegations set forth in Paragraphs 1 through 48 hereof.

**PARTIES**

50. Counterclaim Plaintiff Impax, Inc. ("Impax") is a corporation in good standing incorporated under the laws of the State of Delaware, with its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544. It also has a place of business at 3735 Castor Avenue, Philadelphia, Pennsylvania 19124.

51. On information and belief, Counterclaim Defendant Wyeth, Inc. ("Wyeth") is a corporation incorporated under the laws of the State of Delaware, with its principal place of business in Madison, New Jersey.

**JURISDICTION AND VENUE**

52. Jurisdiction over this counterclaim is proper pursuant to 28 U.S.C. §§ 1331, 1338, and 2201-2202.

53. Because Wyeth sued Impax for patent infringement in this Judicial District, this Court has personal jurisdiction over Wyeth and venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c).

**BACKGROUND**

54. Impax is in the business of bringing lower cost generic drugs to the consumer.

55. Wyeth is an international conglomerate with over $18 billion dollars in revenue and over $3 billion dollars in net income in 2005. On information and belief, after obtaining FDA approval, Wyeth began selling an immediate release dosage form of venlafaxine hydrochloride in 1993. Wyeth still sells immediate release venlafaxine hydrochloride under the name EFFEXOR® for the treatment of depression.

56. On information and belief, Wyeth owns U.S. Patent No. 4,535,186, which claims the drug compound venlafaxine hydrochloride. This patent's expiration date was originally December 13, 2002, but it was extended under 35 U.S.C. § 156 for five years.

57. On March 25, 1996, named inventors Deborah M. Sherman, John C. Clark, John U. Lamer, Steven A. White, their agents and the agents of assignee Wyeth, or its predecessor American Home Products ("AHP"), associated with the prosecution of the Patents-in-Suit (collectively "the Patentees") filed a provisional patent application, U.S. Patent Application No. 60/014,006 ("the '006 application"), with the PTO. Through multiple continuing applications, the Patents-in-Suit eventually resulted from the '006 application.

58. In the '006 application, the Patentees made the following material representation to the PTO with respect to their extended release venlafaxine hydrochloride ("venlafaxine hydrochloride ER" or "venlafaxine ER") that is now claimed in the Patents-in-Suit:

> The use of the one-a-day venlafaxine hydrochloride formulations of this invention reduces by adaptation, the level of nausea and incidence of emesis that attend the administration of multiple daily dosing. In clinical trials of venlafaxine hydrochloride ER, the probability of developing nausea in the course of the trials was greatly reduced after the first week. **Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies**. Thus, in accordance with this use aspect of the invention there is provided a method for reducing the level of nausea and incidence of emesis attending the administration of venlafaxine hydrochloride which comprises dosing a patient in need of treatment with venlafaxine hydrochloride with an extended release formulation of

venlafaxine hydrochloride once a day in a therapeutically effective amount. (emphasis added)

59. On May 16, 1996, Wyeth, AHP, and/or their affiliate Wyeth-Ayerst Laboratories ("WAL") submitted NDA 20-699 to the FDA to obtain approval for a venlafaxine hydrochloride ER called Effexor® XR.

60. In NDA 20-699, as initially submitted to the FDA on May 16, 1996, Wyeth, AHP, and/or WAL indicated that three clinical studies had been completed with respect to its venlafaxine hydrochloride ER. These clinical studies were identified in NDA 20-699 as "600B-208-US", "600B-209-US" and "600B-367-EU", hereafter referred to as "Study 208", Study 209", and "Study 367", respectively.

61. According to the cover letter of NDA 20-699, Study 208 was a double-blind, flexible dose, twelve-week efficacy study of Wyeth/AHP/WAL's 75-150 mg venlafaxine hydrochloride ER, 75-150 mg of Effexor®, which is Wyeth/AHP/WAL's conventional venlafaxine hydrochloride drug, and placebo in outpatients with major depression.

62. According to the cover letter of NDA 20-699, Study 209 was a double-blind, flexible dose, eight-week efficacy study of Wyeth/AHP/WAL's 75-150 mg venlafaxine hydrochloride ER and placebo in outpatients with major depression.

63. According to the cover letter of NDA 20-699, Study 367 was a double blind, fixed dose, eight-week efficacy study of Wyeth/AHP/WAL's 75 and 150 mg venlafaxine hydrochloride ER, 20 mg Paxil, and placebo in outpatients with major depression.

64. Studies 367, 209, and 208 are the "two eight-week and one 12 week clinical studies", respectively, referenced in the '006 application's representation that is quoted in Paragraph 58, above.

65. Of the "two eight-week and one 12 week clinical studies", referenced in the '006 application's representation that is quoted in Paragraph 58, above, only Study

208 included patients receiving venlafaxine hydrochloride ER and conventional venlafaxine hydrochloride tablets. Studies 209 and 367 did not include patients receiving conventional venlafaxine hydrochloride tablets.

66. At the time the '006 application was submitted to the PTO, Study 208, the only study to directly compare patients receiving venlafaxine hydrochloride ER and conventional venlafaxine hydrochloride immediate release tablets, did not indicate statistically significant improvement in nausea. On information and belief, the PTO was never informed during the prosecution of the Patents-in-Suit that the only study directly comparing the two formulations did not show the claimed statistical significance.

67. On information and belief, at the time the '006 application was submitted to the PTO, Studies 209 and 367 did not indicate statistically significant improvement in nausea by patients receiving venlafaxine hydrochloride ER because patients in those studies did not receive conventional venlafaxine hydrochloride tablets. On information and belief, the PTO was never informed during the prosecution of the Patents-in-Suit that these studies individually did not show the claimed statistical significance relating to nausea.

68. On information and belief, at the time the '006 application was submitted to the PTO, Wyeth had not combined or "pooled" the data or results from these three studies to indicate statistically significant improvement in nausea by patients in these studies receiving venlafaxine hydrochloride ER, as compared to patients in these studies receiving conventional venlafaxine hydrochloride tablets.

69. On information and belief, the combination or pooling of the results of patient data in Studies 208, 209, and 367 would be statistically unreliable, and thus an improper basis for reaching a conclusion that there is a statistically significant improvement in nausea by patients in those studies receiving venlafaxine hydrochloride ER, as compared to patients in those studies receiving conventional venlafaxine hydrochloride tablets. On information and belief, the PTO was never informed that

Studies 208, 209, and 367, when considered individually, did not show a statistically significant improvement in nausea.

70. On information and belief, the statements in Paragraph 58 were deceptive and/or misleading because they state or imply that the Patentees, at the time of the '006 application, had results from multiple clinical studies, **each** of which demonstrated that Wyeth/AHP/WAL's venlafaxine hydrochloride ER showed a statistically significant improvement in nausea over conventional venlafaxine hydrochloride tablets.

71. On information and belief, the Patentees at that time had only the results from Study 208 that compared Wyeth/AHP/WAL's venlafaxine hydrochloride ER with conventional venlafaxine hydrochloride tablets, and that study **did not show** a statistically significant improvement in nausea. On information and belief, the failure to disclose to the PTO that the results of Study 208 failed to show a statistically significant improvement in nausea was an omission of material fact.

72. Moreover, the FDA-approved package insert for Wyeth/AHP/WAL's venlafaxine hydrochloride ER, sold as Effexor® XR, does not contain any representation that, in clinical studies, Wyeth/AHP/WAL's venlafaxine hydrochloride ER showed a statistically significant improvement in nausea over conventional venlafaxine hydrochloride tablets, sold as Effexor®, even though the package insert compares Effexor® XR and Effexor® as to the potential for other adverse reactions in the course of their administration.

73. The Patentees' intent to deceive the PTO by submitting the '006 application with the statements quoted in Paragraph 58 can be inferred from Wyeth's omission of the same or similar statements in the package insert for Wyeth/AHP/WAL's venlafaxine hydrochloride ER, sold as Effexor® XR, submitted to the FDA and made publicly available.

74. In light of all relevant circumstances, including those set forth in Paragraphs 57-73, above, at the time the Patentees submitted the '006 application, the

misrepresentation therein that is quoted in Paragraph 58, above, was material and made with the intent to deceive.

75. On information and belief, the Patentees also withheld from the PTO at least one material publication that they knew existed during the prosecution of the Patents-in-Suit.

76. On information and belief, during the prosecution of the Patents-in-Suit, one or more of the Patentees was aware of an article by Lynn A. Cunningham, M.D., entitled *Once-Daily Venlafaxine Extended Release (XR) and Venlafaxine Immediate Release (IR) in Outpatients with Major Depression*, published in the volume 9, no. 3 of the Annals of Clinical Psychiatry in 1997 (hereinafter "the Cunningham article"). The Cunningham article discussed results from Study 208, summarized in Paragraph 61, above, indicated that it was authored on behalf of the "Venlafaxine XR 208 Study Group", and further indicated that Study 208 was supported by Wyeth-Ayerst Research, an affiliate of Wyeth/AHP.

77. The Cunningham article was material to the patentability of the Patents-in-Suit because there is a substantial likelihood that a reasonable examiner would have considered the Cunningham article important in deciding whether to allow one or more claims of each of the Patents-in-Suit to issue, and it is not cumulative of other references provided by the Patentees during the prosecution of the Patents-in-Suit.

78. Among other things, in discussing the results from Study 208, the Cunningham article stated: "The most common adverse event was nausea in 43 (45%) venlafaxine IR-treated [referred to as conventional venlafaxine hydrochloride tablets / Effexor® above], 44 (45%) venlafaxine XR-treated [referred to as Wyeth/AHP/WAL's venlafaxine hydrochloride ER / Effexor® XR above], and 10 (10%) placebo treated patients."

79. On information and belief, the materiality of the Cunningham article to the patentability of the Patents-in-Suit was known by one or more of the Patentees during the

prosecution of the Patents-in-Suit, and one or more of the Patentees failed to disclose the Cunningham article with intent to mislead the PTO.

80. The Patentees' intent to mislead the PTO can be inferred by, among other things, the overwhelming materiality of the Cunningham article and the Patentee's knowledge of that materiality.

81. On information and belief, Wyeth and/or AHP filed the '006 application on March 25, 1996 in an attempt to keep generic venlafaxine competition off the market beyond the expiration of U.S. Patent No. 4,535,186. Through multiple continuing applications, the Patents-in-Suit eventually resulted from the '006 application.

82. On information and belief, Wyeth and/or AHP obtained FDA approval for an extended release venlafaxine hydrochloride dosage form and, through an aggressive marketing campaign, began converting the market from the immediate release product to this extended release form, called EFFEXOR® XR.

83. On information and belief, Teva Pharmaceuticals USA, Inc. ("Teva") filed an ANDA with the FDA to obtain approval to manufacture, use and sell an extended release venlafaxine hydrochloride dosage form, and provided certification to Wyeth that the Patents-in-Suit would not be infringed. Wyeth sued Teva for patent infringement in United States District Court, District of New Jersey. After extensive discovery, a *Markman* hearing was held and that Court issued an order interpreting the claims of the Patents-in-Suit to be limited to a formulation comprising venlafaxine hydrochloride and microcrystalline cellulose. Copies of the Markman Order and Opinion are attached as Exhibit A. Thereafter, Wyeth settled the litigation with Teva but has maintained the terms of the settlement as a secret. As part of the settlement, the Markman Order was vacated.

84. Impax's venlafaxine extended release formulation does not contain microcrystalline cellulose and does not infringe the claims of the Patents-in-Suit.

**FIRST COUNTERCLAIM**
**(Declaratory Judgment of Non-Infringement, Invalidity and Unenforceability of U.S. Patent Nos. 6,274,171, 6,403,120, and 6,419,958)**

85. Impax realleges and incorporates by reference its responses and allegations set forth in Paragraphs 1 through 84 hereof.

86. An actual controversy exists between Wyeth and Impax concerning the Patents-in-Suit, which requires a declaration of rights by this Court. This controversy relates to the alleged infringement, validity, and enforceability of the Patents-in-Suit.

87. Wyeth has asserted ownership of the Patents-in-Suit and that Impax's venlafaxine product will infringe the Patents-in-Suit.

88. Impax has not infringed, is not infringing, and will not infringe any of the claims of the Patents-in-Suit, literally or under the doctrine of equivalents.

89. The Patents-in-Suit and each of the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, utility, anticipation, obviousness, lack of enablement, lack of written description, indefiniteness, and misjoinder/nonjoinder of named inventors in accordance with 35 U.S.C. §§ 101,102, 103, 112, and/or 116, or are invalid pursuant to the judicial doctrine barring double-patenting.

90. Impax is entitled to a declaratory judgment that its venlafaxine hydrochloride extended release product does not infringe the '171 patent.

91. Impax is entitled to a declaratory judgment that its venlafaxine hydrochloride extended release product does not infringe the '120 patent.

92. Impax is entitled to a declaratory judgment that its venlafaxine hydrochloride extended release product does not infringe the '958 patent.

93. Impax is entitled to a declaratory judgment that the '171 patent is invalid and unenforceable.

94. Impax is entitled to a declaratory judgment that the '120 patent is invalid and unenforceable.

95. Impax is entitled to a declaratory judgment that the '958 patent is invalid and unenforceable.

**SECOND COUNTERCLAIM**
**(Declaratory Judgment of Unenforceability of U.S. Patent Nos. 6,274,171, 6,403,120, and 6,419,958 Due to Inequitable Conduct)**

96. Impax realleges and incorporates by reference its responses and allegations set forth in Paragraphs 1 through 84 hereof.

97. An actual controversy exists between Wyeth and Impax concerning the Patents-in-Suit, which requires a declaration of rights by this Court. This controversy relates to the alleged infringement, validity, and enforceability of the Patents-in-Suit.

98. From the time of the '006 application's filing through to the issuance of by the PTO of the latest of the Patents-in-Suit, each of the Patentees had a duty of candor and good faith to disclose to the PTO all information known to that individual that is material to patentability, pursuant to United States patent laws and regulations, including 37 C.F.R. § 1.56(a).

99. The statements quoted in Paragraph 58, above, were a misrepresentation by the Patentees to the PTO and were in contravention of the Patentees' duties to the PTO during the prosecution of the Patents-in-Suit.

100. The failure to disclose the Cunningham article to the PTO was an omission by the Patentees that was in contravention of the Patentees' duties to the PTO during the prosecution of the Patents-in-Suit.

101. The misrepresentation and omission were material to patentability because, among other things, they were relevant to the questions of whether the claims of the Patents-in-Suit, including those covering diminished incidence of nausea, would have been obvious to one of ordinary skill in the art and/or satisfied the utility requirement of 35 U.S.C. § 101.

102. Impax is entitled to a declaratory judgment that the '171 patent is unenforceable.

103. Impax is entitled to a declaratory judgment that the '120 patent is unenforceable.

104. Impax is entitled to a declaratory judgment that the '958 patent is unenforceable.

**PRAYER FOR RELIEF**

WHEREFORE, Impax respectfully requests that this Court enter a Judgment and Order:

A. Dismissing the Complaint, and each count thereof, with prejudice and denying Wyeth any relief whatsoever;

B. Declaring the Patents-in-Suit to be invalid, unenforceable, and/or not infringed by Impax directly, by inducement of infringement, or otherwise;

C. Declaring that Impax has not willfully infringed any of the Patents-in-Suit;

D. Issuing an injunction restraining Wyeth from enforcing or attempting to enforce the Patents-in-Suit against Impax, any of Impax's suppliers, or any of Impax's customers or potential customers;

E. Declaring this case to be an exceptional case pursuant to 35 U.S.C. § 285 or otherwise, and that Impax shall be awarded its costs, together with reasonable attorneys' fees and all of its expenses for defending this suit;

F. Awarding Impax pre-judgment and post-judgment interest as allowed by law;

G. Awarding Impax any such other and further relief as the Court may deem just and proper.

Dated: August 10, 2006

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